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TO: Jasmine Chambers, Group Director  
USPTO FACSIMILE No.: 571-273-0200  
USPTO REFERENCE: Applicant: Sibley et al.  
Serial No.: 09/829,631  
Filed: April 10, 2001  
Title: THE ST-B17 SEROTONIN RECEPTOR  
ATTORNEY: Nancy W. Vensko  
PHONE No.: 805-547-5585  
ATTORNEY DOCKET No.: NIH047.1CP1C1  
TOTAL PAGES: 20 (INCLUDING COVER SHEET)  
DOCKETING AGENT:  
DATE: March 25, 2004

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MESSAGE: *Attached for filing in the above-referenced application are:*

REQUEST FOR REVIEW BY GROUP DIRECTOR OF ART UNIT 1631 in 2 pages; Copy of Interview Summary in 3 pages; Copy of INFORMAL COMMUNICATION FOR DISCUSSION PURPOSES ONLY and marked up copy of MPEP 201.06(c) in 9 pages; Copy of Office Action in 5 pages.

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032504

NIH047.1CP1C1

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Sibley et al.	Group Art Unit 1631
Appl. No.	:	09/829,631	
Filed	:	April 10, 2001	
For	:	THE ST-B17 SEROTONIN RECEPTOR	
Examiner	:	Allen, M.	

REQUEST FOR REVIEW BY GROUP DIRECTOR OF ART UNIT 1631

United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Applicant hereby requests review by the group director of art unit 1631 of the issue whether by containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter and cannot be redesignated as a continuation-in-part. Attached is a copy of an "Interview Summary" indicating, "The requirement for a CIP oath was not resolved and applicant may petition." Applicant requests this review by the group director of art unit 1631 instead of petition to the commissioner without prejudice.

Attached is "Informal Communication for Discussion Purposes Only" faxed in expectation of the interview summarized in "Interview Summary." The issue for review is set forth on page 4. To reiterate, applicant asked for consideration of the attached marked-up copy of MPEP 201.06(c) indicating that the Patent Office strongly recommends that a continuation application *contain* only the desired set of claims rather than *add* the desired set of claims by preliminary amendment. The filing of the desired set of claims (Claims 1-16) rather than adding the desired set of claims by preliminary amendment resulted in the office action (copy attached) determining that the continuation application contains *new matter* and must be *redesignated* as a continuation-in-part. Nevertheless, the MPEP additionally indicates that the prior set of claims

Appl. No. : 09/829,631  
Filed : April 10, 2001

was properly incorporated by reference by a statement in the application transmittal letter specifically enumerating the prior application. There is no dispute that, other than the desired set of claims, the specification is identical to the prior specification (except for the introduction of SEQ ID identifiers). Assuming for the sake of argument that Claims 1-16 did not meet the requirement under 35 USC 112/1 for written description (although they were *not* rejected under 35 USC 112/1 for lack of written description), the claims have been *canceled* and replaced with Claims 17-28. By containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter (although there is a dispute as to whether subsequently-canceled Claims 1-16 meet the requirement under 35 USC 112/1 for written description), the specification of which is otherwise identical to the prior specification (except for the introduction of SEQ ID identifiers), properly incorporates by reference the prior set of claims, and conforms with the procedure strongly recommended by the Patent Office, and therefore cannot be redesignated as a continuation-in-part.

Applicant hereby requests determination by the group director of art unit 1631 of the issue that, by containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter and cannot be redesignated as a continuation-in-part. A shortened statutory period for reply was set to expire 9 March 2004, and the statutory period is set to expire 9 June 2004. A determination in time for Applicant to meet the deadline of 9 April or 9 May 2004 at the latest is respectfully requested.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3/25/04

By: 

Nancy W. Vensko  
Registration No. 36,298  
Attorney of Record  
Customer No. 20,995  
(805) 547-5585

COPY

## Interview Summary

Application No.

09/829,631

Applicant(s)

SIBLEY ET AL.

Examiner

Art Unit

Marianne P. Allen

1631

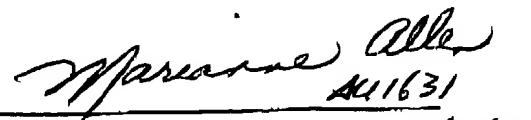
All participants (applicant, applicant's representative, PTO personnel):

(1) Marianne P. Allen.(3) Nancy Vensko.(2) Michael Woodward.(4) Marina Gorday, Eric Ives, David Sibley.Date of Interview: 17 March 2004.Type: a)  Telephonic b)  Video Conference  
c)  Personal [copy given to: 1)  applicant2)  applicant's representative]Exhibit shown or demonstration conducted: d)  Yes e)  No.  
If Yes, brief description: \_\_\_\_\_.Claim(s) discussed: all pending.Identification of prior art discussed: none.Agreement with respect to the claims f)  was reached. g)  was not reached. h)  N/A.Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
 Examiner's signature, if required 3/17/04

## Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**  
 A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135, (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (If Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
 (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**Continuation Sheet (PTOL-419)****Application No. 09/829,631**

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Claim language for part c of claim 17 to avoid a new matter rejection was agreed upon. This portion of the claim will be rewritten using language reflecting that the nucleic acid is isolated from a human genomic library and hybridizes to both probes as set forth in Example 9. The requirement for a CIP oath was not resolved and applicant may petition. Applicant will also amend the claims and specification to reflect the current nomenclature (5-HT-6) for this receptor.

**Knobbe Martens Olson & Bear LLP**

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TO: Examiner Marianne Allen / Supervisor Michael Woodward

USPTO FACSIMILE No.: 571-273-0712 / 571-273-0722

USPTO REFERENCE: Applicant: Sibley et al.

Serial No.: 09/829,631

Filed: April 10, 2001

Title: THE ST-B17 SEROTONIN RECEPTOR

ATTORNEY: Nancy W. Vensko

PHONE No.: 805-547-5585

ATTORNEY DOCKET No.: NIH047.1CP1C1

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MESSAGE: *Attached for filing in the above-referenced application are:*

INFORMAL COMMUNICATION FOR DISCUSSION PURPOSES ONLY in 4 pages; and marked up copy of MPEP 201.06(c) in 4 pages.

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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Sibley et al.
Appl. No.	:	09/829,631
Filed	:	April 10, 2001
For	:	THE ST-B17 SEROTONIN RECEPTOR
Examiner	:	Allen, Marianne P.
Group Art Unit	:	1631

INFORMAL COMMUNICATION FOR DISCUSSION PURPOSES ONLY

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In preparation for the in-person interview scheduled for Tuesday, 17 March 2004, at 10 a.m., please consider the following proposed amendment (for which support is found throughout the specification, for example, at 22:37):

Appl. No. : 09/829,631  
Filed : April 10, 2001

### PROPOSED AMENDMENTS TO THE CLAIMS

Please amend Claim 17 as follows under this proposed amendment:

1-16 PREVIOUSLY CANCELED

17. (Currently amended) An isolated nucleotide sequence encoding a serotonin receptor protein St-B17, said nucleotide sequence being selected from:

- (a) a nucleotide sequence comprising SEQ ID NO:7;
- (b) a nucleotide sequence comprising SEQ ID NO:12;
- (c) a human nucleotide sequence hybridizing under moderate stringency conditions at 6XSSC and 55°C, pH7, to a 1192 bp XmaI-BstXI or a 655 bp BamHI-EagI fragment from SEQ ID NO:7; or
- (d) a nucleotide sequence encoding a protein having the amino acid sequence shown by SEQ ID NO:8 or SEQ ID NO:13.

18. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (a).

19. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (b).

20. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (c).

21. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (d).

22. (Previously presented) A recombinant construct comprising the nucleotide sequence according to Claim 17, operably linked to a heterologous promoter.

23. (Previously presented) The recombinant construct according to Claim 22, which is an expression vector.

24. (Previously presented) The recombinant construct according to Claim 23, which is a eukaryotic expression vector.

25. (Previously presented) A mammalian cell line comprising the nucleotide sequence of Claim 17, said mammalian cell line expressing St-B17 serotonin receptor.

26. (Previously presented) The cell line of Claim 25, wherein said cells are derived from a human.

27. (Previously presented) The cell line of Claim 26, wherein said cells are HEK 293.

Appl. No. : 09/829,631  
Filed : April 10, 2001

28. (Previously presented) An isolated protein encoded by the nucleotide sequence of any of Claims 17-21.

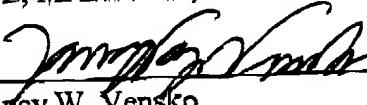
Appl. No. : 09/829,631  
Filed : April 10, 2001

By containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter and cannot be redesignated as a continuation-in-part

Additionally, please consider the attached marked-up copy of MPEP 201.06(c) indicating that the Patent Office strongly recommends that a continuation application *contain* only the desired set of claims rather than *add* the desired set of claims by preliminary amendment. The filing of the desired set of claims (Claims 1-16) rather than adding the desired set of claims by preliminary amendment resulted in the office action determining that the continuation application contains new matter and must be redesignated as a continuation-in-part. Nevertheless, the MPEP additionally indicates that the prior set of claims was properly incorporated by reference by a statement in the application transmittal letter specifically enumerating the prior application. There is no dispute that, other than the desired set of claims, the specification is identical to the prior specification (except for the introduction of SEQ ID identifiers). Assuming for the sake of argument that Claims 1-16 did not meet the requirement under 35 USC 112/1 for written description (although they were *not* rejected under 35 USC 112/1 for lack of written description), the claims have been canceled and replaced with Claims 17-28. By containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter (although there is a dispute as to whether subsequently-canceled Claims 1-16 meet the requirement under 35 USC 112/1 for written description), the specification of which is otherwise identical to the prior specification (except for the introduction of SEQ ID identifiers), properly incorporates by reference the prior set of claims, conforms with the procedure strongly recommended by the Patent Office, and cannot be redesignated as a continuation-in-part.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

By: 

Nancy W. Vensko  
Registration No. 36,298  
Attorney of Record  
Customer No. 20,995  
(805) 547-5585

Dated: 3/5/04

201.06(c)

## MANUAL OF PATENT EXAMINING PROCEDURE

**201.06(c) 37 CFR 1.53(b) and 37 CFR 1.63(d) Divisional-Continuation Procedure [R-1]**

*37 CFR 1.53. Application number, filing date, and completion of application.*

\*\*\*\*\*

(b) *Application filing requirements - Nonprovisional application.* The filing date of an application for patent filed under this section, except for a provisional application under paragraph (c) of this section or a continued prosecution application under paragraph (d) of this section, is the date on which a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75, and any drawing required by § 1.81(a) are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date. A continuing application, which may be a continuation, divisional, or continuation-in-part application, may be filed under the conditions specified in 35 U.S.C. 120, 121 or 365(c) and § 1.78(a).

(1) A continuation or divisional application that names as inventors the same or fewer than all of the inventors named in the prior application may be filed under this paragraph or paragraph (d) of this section.

(2) A continuation-in-part application (which may disclose and claim subject matter not disclosed in the prior application) or a continuation or divisional application naming an inventor not named in the prior application must be filed under this paragraph.

\*\*\*\*\*

*37 CFR 1.63. Oath or Declaration.*

\*\*\*\*\*

(d)(1) A newly executed oath or declaration is not required under § 1.51(b)(2) and § 1.53(l) in a continuation or divisional application, provided that:

(i) The prior nonprovisional application contained an oath or declaration as prescribed by paragraphs (a) through (c) of this section;

(ii) The continuation or divisional application was filed by all or by fewer than all of the inventors named in the prior application;

(iii) The specification and drawings filed in the continuation or divisional application contain no matter that would have been new matter in the prior application; and

(iv) A copy of the executed oath or declaration filed in the prior application, showing the signature or an indication thereon that it was signed, is submitted for the continuation or divisional application.

(2) The copy of the executed oath or declaration submitted under this paragraph for a continuation or divisional application must be accompanied by a statement requesting the deletion of the name or names of the person or persons who are not inventors in the continuation or divisional application.

(3) Where the executed oath or declaration of which a copy is submitted for a continuation or divisional application was originally filed in a prior application accorded status under § 1.47, the copy of the executed oath or declaration for such prior application must be accompanied by:

(i) A copy of the decision granting a petition to accord § 1.47 status to the prior application, unless all inventors or legal representatives have filed an oath or declaration to join in an application accorded status under § 1.47 of which the continuation or divisional application claims a benefit under 35 U.S.C. 120, 121, or 365(c); and

(ii) If one or more inventor(s) or legal representative(s) who refused to join in the prior application or could not be found or reached has subsequently joined in the prior application or another application of which the continuation or divisional application claims a benefit under 35 U.S.C. 120, 121, or 365(c), a copy of the subsequently executed oath(s) or declaration(s) filed by the inventor or legal representative to join in the application.

(4) Where the power of attorney (or authorization of agent) or correspondence address was changed during the prosecution of the prior application, the change in power of attorney (or authorization of agent) or correspondence address must be identified in the continuation or divisional application. Otherwise, the Office may not recognize in the continuation or divisional application the change of power of attorney (or authorization of agent) or correspondence address during the prosecution of the prior application.

(5) A newly executed oath or declaration must be filed in a continuation or divisional application naming an inventor not named in the prior application.

\*\*\*\*\*

## IN GENERAL

37 CFR 1.53(b) is the section under which all applications are filed EXCEPT: (A) an application resulting from entry of an international application into the national stage under 35 U.S.C. 371 and \*\* 37 CFR 1.495; (B) a provisional application under 35 U.S.C. 111(b) and 37 CFR 1.53(c); or (C) a continued prosecution application (CPA) under 37 CFR 1.53(d). Applications submitted under 37 CFR 1.53(b), as well as CPAs submitted under 37 CFR 1.53(d), are applications filed under 35 U.S.C. 111(a). An application filed under 37 CFR 1.53(b) may be an original, a continuation, a divisional, a continuation-in-part, or a substitute. (See MPEP § 201.09 for substitute application.) The application may be for a "utility" patent under 35 U.S.C. 101, a design patent under 35 U.S.C. 171, a plant patent under 35 U.S.C. 161; or a reissue under 35 U.S.C. 251.

37 CFR 1.53(b) is the "default" application. An application that is not (A) the result of the entry of an international application into the national stage after

## TYPES, CROSS-NOTING, AND STATUS OF APPLICATION

201.06(c)

compliance with 35 U.S.C. 371 and \*\* 37 CFR 1.495, (B) a provisional application under 37 CFR 1.53(c), or (C) a CPA under 37 CFR 1.53(d), is an application filed under 37 CFR 1.53(b). An application will be treated as one filed under 37 CFR 1.53(b) unless otherwise designated.

In order to be complete for filing date purposes, all applications filed under 37 CFR 1.53(b) must include a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to 37 CFR 1.71 and at least one claim pursuant to 37 CFR 1.75, and any drawing required by 37 CFR 1.81(a). The statutory filing fee and an oath or declaration in compliance with 37 CFR 1.63 (and 37 CFR 1.175 (if a reissue) or 37 CFR 1.162 (if for a plant patent)) are also required by 37 CFR 1.51(b) for a complete application, but the filing fee and oath or declaration may be filed after the application filing date upon payment of the surcharge set forth in 37 CFR 1.16(e). See 37 CFR 1.53(f).

Any application filed on or after December 1, 1997, which is identified by the applicant as an application filed under 37 CFR 1.60 will be processed as an application under 37 CFR 1.53(b) (using the copy of the specification, drawings and signed oath/declaration filed in the prior application supplied by the applicant). Any submission of an application including or relying on a copy of an oath or declaration that would have been proper under 37 CFR 1.60 will be a proper filing under 37 CFR 1.53(b).

A new application containing a copy of an oath or declaration under 37 CFR 1.63 referring to an attached specification is indistinguishable from a continuation or divisional application containing a copy of an oath or declaration from a prior application submitted pursuant to 37 CFR 1.63(d). Unless an application is submitted with a statement that the application is a continuation or divisional application, see 37 CFR 1.78(a)(2), the Office will process the application as a new non-continuing application. Applicants are advised to clearly designate any continuation, divisional, or continuation-in-part application as such to avoid the issuance of a filing receipt that does not indicate that the application is a continuation, divisional, or continuation-in-part.

## OATH/DECLARATION

37 CFR 1.63(d) provides that a newly executed oath or declaration is not required in a continuation or divisional application filed by all or by fewer than all of the inventors named in a prior nonprovisional application containing a signed oath or declaration as required by 37 CFR 1.63, provided that a copy of the signed oath or declaration filed in the prior application is submitted for the continuation or divisional application and the specification and drawings filed in the continuation or divisional application do not contain any subject matter that would have been new matter in the prior application. The copy of the oath or declaration must show the signature of the inventor(s) or contain an indication thereon that the oath or declaration was signed (e.g., the notation "/s/" on the line provided for the signature).

It is not necessary to have the inventor sign a new oath or declaration merely to include a reference to the duty of disclosure if the parent application was filed prior to January 1, 1978, to indicate that the inventor has reviewed and understands the contents of the application if the parent application was filed prior to October 1, 1983, or to indicate the inventor's post office address if the parent application was filed prior to December 1, 1997, and the inventor's mailing or post office address is identified elsewhere in the application.

When a copy of an oath or declaration from a prior application is filed in a continuation or divisional application under 37 CFR 1.53(b), special care should be taken by the applicant to ensure that the copy is matched with the correct application file. Applicant should file the copy of the oath or declaration with a cover letter explaining that the copy of the oath or declaration is for the attached application or for a previously-filed 37 CFR 1.53(b) application (identified by application number which consists of a two-digit series code, e.g., 08/, and a six-digit serial number, e.g., 123,456). An adhesive label may be attached to the front of the copy of the oath or declaration. The label should clearly state that the copy of the oath or declaration is intended for the attached application submitted therewith or for Application No. XX/YYY,YYY. During initial processing, attachments (e.g., a cover letter) to application papers may be separated. Therefore, applicant should not rely solely upon a cover letter. Note: 37 CFR 1.5(a) states that no

201.06(c)

## MANUAL OF PATENT EXAMINING PROCEDURE

correspondence relating to an application should be filed prior to receipt of the application number information from the Patent and Trademark Office.

37 CFR 1.63(d) requires a copy of the signed oath or declaration from the prior application. In instances in which the oath or declaration filed in the prior application is itself a copy of an oath or declaration from a prior application, either a copy of the copy of the oath or declaration in the prior application or a direct copy of the original oath or declaration is acceptable, as both are a copy of the oath or declaration in the prior application, see 37 CFR 1.4(d)(1)(ii).

The patent statute and rules of practice do not require that an oath or declaration include a date of execution, and no objection should be made to an oath or declaration because it lacks either a recent date of execution or any date of execution. The applicant's duty of candor and good faith including compliance with the duty of disclosure requirements of 37 CFR 1.56 is continuous and applies to the continuing application.

A newly executed oath or declaration is required in a continuation or divisional application filed under 37 CFR 1.53(b) naming an inventor not named in the prior application, and in a continuation-in-part application.

## SPECIFICATION AND DRAWINGS

A continuation or divisional application may be filed under 35 U.S.C. 111(a) using the procedures set forth in 37 CFR 1.53(b), by providing: (A) a copy of the prior application, including a copy of the signed oath or declaration in such prior application, as filed; (B) a new specification and drawings and a copy of the signed oath or declaration as filed in the prior application provided the new specification and drawings do not contain any subject matter that would have been new matter in the prior application; or (C) a new specification and drawings and a newly executed oath or declaration provided the new specification and drawings do not contain any subject matter that would have been new matter in the prior application. If a continuation or divisional application filed with a newly executed oath or declaration contains subject matter that would have been new matter in the prior application, the application will have to be amended to indicate that it is a continuation-in-part application rather than a continuation or a divisional application.

The specification and drawings of a continuation or divisional application filed under 37 CFR 1.53(b) are not limited to a reproduction or "true copy" of the prior application, i.e., the applicant may revise the specification for clarity or contextual purposes vis-à-vis the specification originally filed in the prior application in the manner that an applicant may file a substitute specification, see 37 CFR 1.125, or amend the drawings of an application so long as it does not result in the introduction of new matter. It is the applicant's responsibility to review any new specification or drawings submitted for a continuation or divisional application under 37 CFR 1.53(b) and 37 CFR 1.63(d) to determine that it contains no new matter. An applicant is advised to simply file a continuing application with a newly executed oath or declaration when it is questionable as to whether the continuing application adds material that would have been new matter if presented in the prior application. If one or more claims are allowed in the continuation or divisional application which are directed to matter shown and described in the prior nonprovisional application but not claimed in the prior application, the applicant should be required to file a supplemental oath or declaration under 37 CFR 1.67(b).

Where a copy of the oath or declaration from a prior application was filed in a continuation or divisional application, if the examiner determines that new matter is present relative to the prior application, the examiner should so notify the applicant in the next Office action (preferably the first Office action). The examiner should require: (A) a new oath or declaration along with the surcharge set forth in 37 CFR 1.16(e); and (B) that the application be redesignated as a continuation-in-part.

>Any utility or plant patent application, including any continuing application, that will be published pursuant to 35 U.S.C. 122(b) should be filed under 37 CFR 1.53(b) with a specification (including the claims), and drawings, that the applicant would like to have published. This is important because the Office will generally publish the specification (including the claims) and drawings as filed and, under 35 U.S.C. 154(d), a patentee may obtain provisional rights if the invention claimed in a patent is substantially identical to the invention claimed in the application publication. Filing a continuing application under 37 CFR 1.53(b) with a preliminary amendment (which makes

## TYPES, CROSS-NOTING, AND STATUS OF APPLICATION

201.06(c)

all the desired changes to the specification, including adding, deleting or amending claims) is NOT recommended because the changes made by the preliminary amendment will generally not be reflected in the patent application publication even if the preliminary amendment is referred to in an oath or declaration. As noted above, a continuation or divisional application filed under 37 CFR 1.53(b) may be filed with a new specification and corrected drawings, along with a copy of an oath or declaration from a prior (parent) application, provided the new specification and drawings do not contain any subject matter that would have been new matter in the prior application. Thus, the new specification and corrected drawings may include some or all of the amendments entered during the prosecution of the prior application(s), as well as additional amendments submitted for clarity or contextual purposes, and a new set of claims. In order to have a patent application publication of a continuation or divisional application contain only a desired set of claims, rather than the set of claims in the prior application, it is strongly recommended that the continuation or divisional application be filed under 37 CFR 1.53(b) with a new specification containing only the desired set of claims. If the continuation or divisional application is filed with a copy of the specification from the prior application along with a preliminary amendment which cancels, amends and/or adds new claims, publication of the application, as amended, would only occur if a copy of the specification (with the amended set of claims) was also submitted through the Office's Electronic Filing System (EFS).<



## INCORPORATION BY REFERENCE

In a continuation or divisional application, the safeguard (petition and fee under former 37 CFR 1.60(b)) concerning the filing of an application lacking all of the pages of the specification or sheets of drawings of the prior application has not been retained in 37 CFR 1.53(b) since the specification and drawings of a continuation or divisional application are not limited to a reproduction or a "true copy" of the prior application. As a safeguard, however, an applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby

incorporated herein by reference." The statement may appear in the specification or in the application transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference.

A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed.

For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. >An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980).<

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,631	04/10/2001	David R. Sibley	NIH047.1CPIC1	7640

20095 7590 12/09/2003

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ALLEN, MARIANNE P	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/829,631	SIBLEY ET AL.
	Examiner	Art Unit
	Marianne P. Allen	1631

~ The MAILING DATE of this communication appears on the cover sheet with the correspondence address ~  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. 513).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on 23 June 2003.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 17-28 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 17,20 and 22-28 is/are rejected.

7)  Claim(s) 18,19 and 21 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)  The translation of the foreign language provisional application has been received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's arguments filed 6/23/03 have been fully considered but they are not persuasive.

Claims 17-28 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Oath/Declaration*

It is maintained that in view of originally filed claims 1-16 in this application, this application remains a continuation-in-part application and a new oath is required as set forth in the prior Office action. The status as a continuation-in-part application will not change even if the presently pending or any future claims have basis in the parent applications and are granted benefit of that priority date. Once again, as filed, this application constituted a continuation-in-part application. Applicant's arguments on this point are not germane nor do they dispute that originally filed claims 1-16 were not supported by the parent application.

#### *Priority*

Applicant is requested to update the status of all applications referenced throughout the specification.

#### *Claim Rejections - 35 USC § 112*

Claims 17, 20, and 22-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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For the purposes of discussing the new matter rejection, basis for the present claims will be considered with respect to basis in WO 94/10310. All page references will be with respect to this document.

Claim 17, part (c) is directed to nucleotide sequences that hybridize under particular conditions and encode a serotonin receptor protein St-B17.

Example 9 at page 22 discloses using the rat St-B17 serotonin receptor sequence fragments and conditions named in part (c) to clone the human sequence from a particular human genomic library (Stratagene # 946205). There is no contemplation of generic St-B17 sequences encoding receptors from other species that would hybridize to the recited restriction fragments under the recited conditions. This specific example is not considered to demonstrate contemplation of the generic invention now claimed.

None of the portions of the specification pointed to by applicant show contemplation for the embodiments encompassed by part (c).

#### *Claim Rejections - 35 USC § 102*

Claims 17, 20, and 22-28 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Sibley et al. (WO 94/10310) or Sibley et al. (EP 0 558,912 B1).

As presently written, these claims are entitled to benefit of the instant filing date of 4/10/01 and both Sibley et al. (WO 94/10310) and Sibley et al. (EP 0 558,912 B1) are valid prior art under 35 U.S.C. 102(b). Claim 17, part (c) is not supported by the instant application nor any of the priority documents and is properly denied benefit.

Both Sibley et al. (WO 94/10310) and Sibley et al. (EP 0 558,912 B1) disclose cloning and expression of the rat and human St-B17 serotonin receptor. Vectors and host cells are

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disclosed. The sequences disclosed would meet the limitations of part (c) of claim 17. See abstract, claims, and figures. In particular, claim 1 part (c) of Sibley et al. (EP 0 558,912 B1) reflects the same language as instant claim 17, part (c). It is noted that the instant application does not claim priority to this document and what is contemplated in this European patent is not found in the instant application, parent application 08/428,242, PCT/US93/10296 nor parent application 07/970,338.

***Conclusion***

Claims 18, 19, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Marianne P. Allen*  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa